

REMARKS

In response to the final Office Action dated September 24, 2003, in connection with the above-identified application, Applicant respectfully requests entry of this amendment under the provisions of 37 C.F.R. § 1.116(a) in that the amendment and remarks below place the application and the claims in condition for allowance and in better form for consideration on appeal. Claims 1-19, 22-24, 44 and 47-54 are pending in this application. Claims 1-19, 22-24, 44 and 47-54 have been elected. Claims 1-10, 13-19, 22-24, 44 and 47-54 have been rejected under 35 U.S.C. §102. Claims 11, 12, 44 and 47-52 have been rejected under 35 U.S.C. §103. Upon entry of this amendment, Claims 1, 4, 5, 44, 47 and 53 have been amended, Claims 6 and 7 have been cancelled without prejudice and Claims 55-74 have been added. Reconsideration and reexamination is respectfully requested.

Rejection Under 35 U.S.C. §102

The Examiner has rejected Claims 1-10, 13-19, 22-24, 44 and 47-54 under 35 U.S.C. 102(b) as being anticipated by Lee et al., U.S. Patent #6,010,521. This rejection is respectfully traversed. However, in an effort to expedite prosecution of this application and pass the claims to allowance at an earliest possible date, Applicant has amended Claims 1, 4, 5, 44, 47 and 53 in a manner consistent with the Examiner's suggestions during a telephone conference between the Examiner and Applicant's representative on December 8, 2003. Applicant expresses deep gratitude for the courtesy extended by the Examiner during the telephone conference.

Claim 1 has been amended to clarify the "at least one substance" and the "detrimental change" as requested by the Examiner. As amended, Claim 1 now recites a catheter having, *inter alia*, first and second materials wherein the second material has a permeability lower than polyethylene for CO₂ to prevent obstructions from forming in the formulation. Independent Claims 44, 47 and 53 recite similar features. These features are not disclosed or suggested in Lee.

Lee is directed toward a catheter formed in part from a multilayered member having a first layer fusion bonded to another catheter component. The first layer is bonded to the skirt of an inflatable balloon. The multilayered member also has a second layer adjacent the first

layer having a melting point greater than the first layer so that the multilayered member of the catheter is not deformed when the other catheter component is fusion bonded to the first layer of the multilayered member. Lee does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for CO₂ to prevent obstructions from forming in the formulation.

Claim 54 recites a catheter having, *inter alia*, an outer layer and a barrier layer wherein the inner surface of the outer layer covers the outer surface of the barrier layer only at the distal end of the catheter. This feature is not disclosed or suggested in Lee.

Lee discloses a catheter where the inner layer and outer layer are coincident with one another over the length of the catheter. In some embodiments of the Lee catheter, the outer layer extends beyond the distal end of the inner layer to form a non-traumatic distal tip. There is no disclosure or suggestion in Lee of a catheter where the inner surface of the outer layer covers the outer surface of the barrier layer only at the distal end of the catheter.

Claims 55-74 have been added and reflect the features suggested by the Examiner during the December 8, 2003, telephone conference. Independent Claim 55 recites a catheter having, *inter alia*, first and second materials wherein the second material has a permeability lower than polyethylene for phenolic compounds to prevent obstructions from forming in the formulation. This feature is not disclosed or suggested in Lee. As stated previously, Lee discloses a multilayered member having a first layer that is bonded to the skirt of an inflatable balloon. The multilayered member also has a second layer adjacent the first layer having a melting point greater than the first layer so that the multilayered member of the catheter is not deformed when the other catheter component is fusion bonded to the first layer of the multilayered member. Lee does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for phenolic compounds to prevent obstructions from forming in the formulation. Thus, Claim 55 is allowable over the Lee reference. Claims 56-74 depend either directly or indirectly from Claim 55 and are allowable for at least the same reasons as Claim 55.

Accordingly, there are limitations in independent Claims 1, 44, 47, 53, 54 and 55 not disclosed or suggested in Lee. Thus, Lee cannot anticipate these claims. Likewise, Lee cannot anticipate claims 2-10, 13-19 and 22-24, which depend directly or indirectly from Claim

1; Claims 48-52, which depend directly or indirectly from Claim 47, and Claims 56-74, which depend directly or indirectly from Claim 55 for at least the same reasons as Claim 1.

Rejection Under 35 U.S.C. §103

The Examiner has rejected Claims 11 and 12 under 35 U.S.C. 103(a) as being unpatentable over Lee et al., U.S. Patent #6,010,521, in view of Bogert et al, U.S. Patent #6,096, 012. This rejection is respectfully traversed.

Claims 11 and 12 both depend from Claim 1 and add to Claim 1 that the second material is capillary glass and diamond, respectively. As stated above, Lee does not disclose or suggest all of the features recited in amended Claim 1, and, thus, by extension, Claims 11 and 12. Moreover, not all of the features of Claims 11 and 12 are disclosed or suggested in Bogert.

Bogert is directed toward a disposable, coated, unitarily constructed, plastic catheter and cannula structure in which the tip end forms a sharp needle point coated with a hard material to facilitate insertion into a patient. In Bogert, the catheter is designed such that the sharp-tipped portion can penetrate the skin of a patient with minimal force. Bogert does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. In fact, as with Lee, the concept of permeability can not be found anywhere in the entire Bogert patent.

Thus, neither Lee nor Bogert disclose or suggest, individually or in combination, all of the limitations of Claims 11 and 12. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d at 1438 (Fed. Cir. 1991). Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to Claims 11 and 12. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 11 and 12.

The Examiner has rejected Claims 44 and 47-50 under 35 U.S.C. 103(a) as being unpatentable over Lee et al., U.S. Patent #6,010,521, in view of Polaschegg et al, U.S. Patent #4,966,579. This rejection is respectfully traversed.

As stated above, Lee does not disclose or suggest all of the features recited in amended Claims 44 and 47 and, by extension, Claims 48-50, which depend either directly or indirectly from Claim 47. Moreover, not all of the features of Claims 44 and 47-50 are disclosed or suggested in Polaschegg.

Polaschegg is directed toward an apparatus for dosed, continuous, simultaneous infusion of several solutions or medicaments which are arranged in a plurality of containers or syringes. The Polaschegg device is a complex piece of machinery and does not delve into the intricacies of catheter design. Polaschegg does not disclose or suggest a catheter having first and second materials wherein the second material has a permeability lower than polyethylene for at least one substance that could cause detrimental change in the properties or composition of a formulation. In fact, as with Lee and Bogert, the concept of permeability can not be found anywhere in the entire Polaschegg patent.

Thus, neither Lee nor Polaschegg disclose or suggest, individually or in combination, all of the limitations of Claims 44 and 47-50. Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to Claims 44 and 47-50. Applicant respectfully requests that the Examiner withdraw the rejection of Claims 44 and 47-50.

The Examiner has rejected Claims 51 and 52 under 35 U.S.C. 103(a) as being unpatentable over Lee et al., U.S. Patent #6,010,521, in view of Polaschegg et al, U.S. Patent #4,966,579, and further in view of Bogert et al, U.S. Patent #6,096, 012. This rejection is respectfully traversed.

Claims 51 and 52 depend directly from amended Claim 47. As stated above, neither Lee, Polaschegg or Bogert, disclose or suggest, individually or in combination, all of the limitations of Claim 47 and, by extension, Claims 51 and 52. Accordingly, the Examiner has not established a *prima facie* case of obviousness with respect to Claims 51 and 52.

Also, new Claim 55-74 cannot be considered obvious in view of Lee, Polaschegg or Bogert. As stated above, there are features recited in Claims 55-74 that are not disclosed or suggested, individually or in combination, in Lee, Polaschegg or Bogert. Accordingly, a *prima*

facie case of obviousness cannot be established with respect to Claims 55-74 in light of these references.

Applicant respectfully submits that the foregoing amendments are made to comply with requirements of form, and thus may be admitted under 37 C.F.R. § 1.116(a). With respect to those amendments deemed to touch the merits, admission is requested under 37 C.F.R. § 1.116(b). In this connection, the amendments were not earlier presented because they are in response to the matters pointed out for the first time in the Final Office Action. Lastly, admission is requested under 37 C.F.R. § 1.116(a) as presenting the rejected claims in better form for consideration on appeal.

Therefore, the Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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